510(k) Summary

per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Beth Torok Principal Regulatory Affairs Specialist Phone: 763-494-1273 Fax: 763-494-2222 e-mail: beth.torok@bsci.com
Date Prepared	06 September 2013
Proprietary Name	Gladiator™ Elite PTA Balloon Dilatation Catheter
Common Name	Percutaneous Catheter
Product Code	LIT – Catheter, Angioplasty, Peripheral, Transluminal
Classification	Class II, 21 CFR Part 870.1250 – Percutaneous Catheter
Predicate Device(s)	Gladiator PTA Balloon Dilatation Catheter K113681 11 January 2012
Device Description	Gladiator Elite is an over-the-wire balloon catheter with a dual lumen shaft design. One lumen is used to pass the catheter over 0.035" guidewires. The second lumen communicates with the balloon and is used to inflate and deflate the balloon during the procedure. The guidewire lumen and the balloon lumen terminate at the proximal end of the catheter in a Y-connector manifold with luer lock fittings. There are radiopaque marker bands located under the balloon shoulders to aid in positioning the system during the procedure. A coating is applied to the balloon to enhance insertion and withdrawal performance. The tip of the catheter is gradually tapered to facilitate advancement of the catheter through the stenosis.
Intended Use/Indications for Use	The Gladiator Elite Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Gladiator Elite Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.
Comparison of Technological Characteristics	The Gladiator Elite PTA Balloon Dilatation Catheter incorporates substantially equivalent device materials, catheter configuration, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate device.

Comparison to Predicate Device:

Characteristic	Proposed compared to Predicate
Components	Same components, configuration, design and function.
Materials	Same materials. Balloon contains an additional material not new to the device.
Packaging	Same packaging materials and configuration.
Sterilization Method/SAL	Same method and level of assurance.
Guidewire Compatibility	Same compatibility.
Balloon Diameters & Lengths	Same sizes.
Effective Length	Same length catheters.
Rated Burst Pressure (RBP)	Same RBP.

Performance Data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following biocompatibility tests support the Gladiator Elite PTA Balloon Dilatation Catheter;

Guinea Pig Maximization Sensitization	Intracutaneous Reactivity
In vitro Hemocompatibility Assay	Acute Systemic Injection
Hemolysis Assay: Direct Contact Method	Materials Mediated Rabbit Pyrogen
Complement Activation C3a and SC5b-9 Assay	Ames Mutagenicity
Mouse Lymphoma	In vitro Cytotoxicity: MEM Elution
Partial Thromboplastin Time (PTT)	USP Physicochemical Test for Plastics
Natural Rubber Latex	

The following in-vitro performance tests were completed;

Balloon Compliance	Balloon Multiple Inflation
Balloon Nominal Diameter	Burst in a Stent
Rated Burst Pressure	Balloon Multiple Inflation in a Stent
Balloon Burst Mode	Initial Sheath Insertion Force
Proximal Bond Tensile	Sheath Withdrawal
Balloon Protector (Wingtool) Removal Force	Crossing Profile
Particulate Release	

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Gladiator Elite PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Gladiator PTA Balloon Dilatation Catheter as submitted in K113681.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

Boston Scientific Corporation
c/o Ms. Anne V. Rossi
Regulatory Affairs Fellow
One Scimed Place
Maple Grove, MN 55311-1566

Re: K132810
Trade/Device Name: Gladiator™ Elite PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: January 24, 2014
Received: January 27, 2014

Dear Ms. Rossi,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K132810

Indications for Use

510(k) Number (if known): _____

Device Name: Gladiator™ Elite Over-the-Wire PTA Balloon Dilatation Catheter

Indications for Use:

The Gladiator Elite Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Gladiator Elite Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kenneth J. Cavanaugh -S